

**SYRINGE WITH ELECTRONIC REPRESENTATION OF PARAMETERS**

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**Abstract**

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A syringe having a dose setting mechanism, a button which can be operated to inject a set dose, a switch operated at a time between the start and the completion of the injection and an electronic representation of parameters such as magnitudes of the set dose and the latest injected dose, which syringe further has a stop watch which is reset and started when the switch is operated. The status of the watch function is electronically represented and is together with the electronic represented parameters reproduced in a display showing the number of hours passed since the operation of the switch by switching on a corresponding number of 30 DEG segments of a circle. Dose sizes are shown by common Arabic numerals.

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## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<b>(51) International Patent Classification <sup>6</sup> :</b> <b>A61M 5/178, 5/20</b>	<b>A1</b>	<b>(11) International Publication Number:</b> <b>WO 97/30742</b> <b>(43) International Publication Date:</b> 28 August 1997 (28.08.97)
<b>(21) International Application Number:</b> PCT/DK97/00077 <b>(22) International Filing Date:</b> 20 February 1997 (20.02.97) <b>(30) Priority Data:</b> 0199/96 23 February 1996 (23.02.96) DK <b>(71) Applicant (for all designated States except US):</b> NOVO NORDISK A/S [DK/DK]; Novo Allé, DK-2880 Bagsværd (DK). <b>(72) Inventors; and</b> <b>(75) Inventors/Applicants (for US only):</b> JENSEN, Jens, Møller [DK/DK]; Nyhavn 39, DK-1051 Copenhagen K (DK). POULSEN, Jens, Ulrik [DK/DK]; Virumgade 54 C, DK-2830 Virum (DK). SMEDEGAARD, Jørgen, K. [DK/DK]; Bernhard Bangs Allé 22, DK-2000 Frederiksberg (DK). <b>(74) Common Representative:</b> NOVO NORDISK A/S; Corporate Patents, Novo Allé, DK-2880 Bagsværd (DK).		<b>(81) Designated States:</b> AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, US, UZ, VN, ARIPO patent (KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).  <b>Published</b> <i>With international search report.</i>

**(54) Title:** SYRINGE WITH ELECTRONIC REPRESENTATION OF PARAMETERS**(57) Abstract**

A syringe having a dose setting mechanism, a button which can be operated to inject a set dose, a switch operated at a time between the start and the completion of the injection and an electronic representation of parameters such as magnitudes of the set dose and the latest injected dose, which syringe further has a stop watch which is reset and started when the switch is operated. The status of the watch function is electronically represented and is together with the electronic represented parameters reproduced in a display showing the number of hours passed since the operation of the switch by switching on a corresponding number of 30° segments of a circle. Dose sizes are shown by common Arabic numerals.



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## SYRINGE WITH ELECTRONIC REPRESENTATION OF PARAMETERS

5 The invention relates to syringes of the type having a dose setting mechanism, a button operable to carry out an injection movement to inject the set dose, a switch operated when an injection is made at the start or at the completion of this injection or at a time between the start and the completion of this injection, and an electronic representation of relevant parameters such as of a set dose and the latest injected dose.

10 The electronic representation usually is in the form of an electronic display showing numbers indicating the numbers of international units of the medicament in the set and the latest injected dose. However, to show consideration to visually impaired people the electronic representation may be attended to by a speech circuit which pronounces the numbers instead of displaying them. Alternatively the numbers may also by electronic or electro-mechanical means be trans-  
15 formed into a tactile code, or the numbers may be communicated through a suitable interface for presentation by any external means, e.g. TV screens, PC monitors etc.

Diabetics who have to frequently inject themselves with insulin may wish to know not only the magnitude of the latest injected dose but also how long time has passed since the latest  
20 injection was made.

From EP 87 491 is known a kit comprising a storage box for insulin vials and a syringe which kit is provided with a timer device by which the time for the latest injection may be set manually. Further the hour for the next injection may be set and the timing device may function as an alarm  
25 clock sounding an alarm when it is time for this next injection. However, in a world where people may in short time cross from one time zone to another and the hours in the time zones even may shift from summer to winter time a reference to the hour is uncertain. Here the count down is more adequate but has the drawback that unless you are ready to take an injection immediately when the alarm sounds you will have a new time account to handle, e.g. for how long  
30 an interval was the alarm set and how long time has passed from the sound of the alarm till the injection is actually made.

It is an object of the application to provide a syringe by which these problems are overcome.

Another object of the invention is to have the relevant parameters represented electronically in a way which enables presentation of these parameters in any preferred way. When a LCD display is chosen the digits may be arbitrarily large as their size are not dependent on the magnitude of the mechanical movement represented by the displayed parameter. The information may be transformed into sound or Braille and may be transmitted to external displays.

This is obtained by a syringe having a dose setting mechanism, a button operable to carry out an injection movement to inject the set dose, a switch operated at the start or at the completion of the injection or at a time between the start and the completion of the injection, and an electronic representation of relevant parameters such as of a set dose and latest injected dose, which syringe is according to the invention characterised in, that it comprises a stop watch which is reset and started when the switch is operated, the status of the stop watch function being electronically represented.

When the stop watch counts the number of hours passed from the latest operation of the switch, i. e. from the latest injection, the user may have a comprehensive view of the time which has passed after the latest injection and the size of this last injection. In this way the user is able to set the next dose with regard to these parameters.

When according to the invention a stop watch is reset and started when the switch is operated, e.g. when the injection movement of the button is completed, the watch is automatically started when an injection is made.

According to an embodiment of the invention the status of the stop watch immediately after the operation of the switch is displayed in a way indicating the number of seconds passed after said operation. This may guide the user to keep the injection needle inserted for some seconds after the button has been pressed home which is desirable to allow the injected liquid to be adopted in the tissue before the needle is drawn out, as the liquid may else leak out through the wound left by the needle so that a dose minor than the intended one is absorbed in the body, and is desirable to allow the full dose to be completely delivered by the syringe. A resting time of 4 to 10 and preferably 6 seconds has been shown to be appropriate.

From WO 90/09202 a syringe is known by which a timer counts the seconds passing from the beginning of the injection till this injection is completed. This time, however is of less importance

and it is recommended that the user himself controls the injection speed as he immediately may feel if the liquid is injected faster than the tissue can absorb it.

5 According to an embodiment of the syringe according to the invention the electronic representation of the status of the stop watch is an electronic display on which the status is indicated by segments of which one is activated for each hour passed from the completion of the injection, i.e. after the switch was operated.

10 During the first seconds of the running of the stop watch the electronic display may be used for guiding the patient to maintain the needle inserted for some seconds after the injection movement of the button has been completed. This guiding is obtained by activating one or more segments per second passing immediately after the completion of the injection movement of the button until all segments of the dial is activated. Thereafter all the segments are deactivated and are reactivated one by one for each hour passing after the switch was operated, i.e. since the  
15 latest injection was made.

According to an embodiment of the invention the electronic display may comprise twelve circle segments forming a watch dial and when the segments are activated one per hour passed after the operation of the switch it is done in a sequence so that the segment between the twelve  
20 o'clock position and the one o'clock position is activated after one hour, a segment between one o'clock and the two o'clock position is further activated after two hours, and so on.

The same watch dial may conveniently be used to indicate the course of the first few seconds after the operation of the switch with the difference that two segments are activated for each  
25 second passed after the home pressing of the button. The two segments first activated may e.g. be the segments between the five o'clock and six o'clock position and between the six o'clock and seven o'clock position, the next two segments may be the segments between the seven and eight o'clock and the four and five o'clock positions and so on so that all the segments in the dial are activated during six seconds beginning from the bottom of the dial and spreading  
30 clockwise and counter clockwise to the top of the dial. When all the segments has been activated during these first seconds of the running of the stop watch they are switched off and are then reactivated, one per hour passed since the operation of the switch.

According to an embodiment of the syringe according to the invention said syringe may be equipped with a memory storing data comprising the sizes of a number of previously injected doses and the time intervals between these doses and the insulin type used by the injections.

5 In the following the invention will be further described with references to the drawing, wherein

Figure 1 shows a display window with none of the display elements activated,

Figure 2 shows the display in figure 1 during a test activating all display elements,

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Figure 3 shows the display in figure 1 showing the size of a set dose,

Figure 4 shows the display in figure 1 five seconds after the injection button has been pressed home,

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Figure 5 shows the display in figure 1 immediately the end of an injection course,

Figure 6 shows the display in figure 1 four hours after the injection of 20 units of a medicine.

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Figure 1 shows an embodiment of a display window of a display displaying the electronic representations of parameters so as set dose, latest injected dose, and status of the stop watch according to the invention. None of the display elements are activated. This condition only occurs when the device due to malfunction or expiry is not operative or when the display during storage is switched off to save the battery.

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When the device is made ready for use e. g. by removing a protective cap a short test function may be run by which all the elements of the display are activated to make sure that they all work. This condition is shown in figure 2. The display elements comprise digits 1 for indication of set doses, segments 2 for indicating time passed, and a dial indicating circle 3 indicating that the hour counting stop watch is running.

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When the dose setting mechanism of the syringe is operated the display change to the appearance shown in figure 3 where the size of the dose set is shown as a number representing the number of units set. As long as the injection is not yet initiated the set dose may be varied.

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When the dose is set the needle of the syringe is inserted into the subcutaneous tissue of the user and an injection button is pressed home. When the button is totally pressed home, a switch is activated which switch activates a stop watch counting the hours passing after the completion of said pressing of the button. In the embodiment with the shown display the number of seconds are counted and displayed from the moment when the injection was completed to allow the user to ensure that the needle remains inserted some seconds after the end of the injection is finished. It is recommended to leave the needle in the tissue for 5-10 seconds after the injection is finished to make sure that the full dose has been delivered and that the injected liquid has been distributed in the tissue so that it is not pressed out through the needle wound. Figure 4 shows the display after five seconds as two segments of the display is activated per second passed after the button has been pressed home which is taken as an indication of the fact that the injection is finished. The activation of the segments starts from the bottom of the dial and progresses by two segments per second one on each side of the dial. The successive activation in figure 4 is illustrated by the using a lighter grey tone for the latest activated segments. After six seconds all the segments of the dial are activated and the display now change to the condition shown in figure 5. Here the circle 3 is activated to indicate that the stop watch which counts the hours from the end of the injection is running but as less than one hour has passed, no segments are activated yet. The reading of the display now indicates the magnitude of the latest injection and the time passed since this injection. Figure 6 shows the display four hours after 20 units of a medicine were injected.

The first stop watch keeps running until next time the dose setting mechanism is operated. The operation of the dose setting mechanism will change the display to the figure 3 appearance, only the display will not show the number "20" but the magnitude of the dose now set.

When the protective cap is mounted the display is switched off and when the cap is removed the display is switched on. When switched on the display will shortly show the test appearance according to figure 2 and then change to the appearance shown in figure 6 showing the latest injected dose and the number of hours passed since this injection.



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## CLAIMS

1. A syringe having a dose setting mechanism, a button operable to carry out an injection movement to inject a set dose, a switch operated at the start or at the completion of an injection  
10 or at a time between the start and the completion of the injection, and an electronic representation of relevant parameters such as of a set dose and the latest injected dose, characterised in that it comprises a stop watch which is reset and started when the switch is operated, the status of the stop watch function being electronically represented.
- 15 2. A syringe according to claim 1, characterised in that the switch is operated to reset and start the stop watch when the dose setting mechanism has completed the movement required to inject a set dose.
3. A syringe according to claim 1 or 2, characterised in that the stop watch counts the number  
20 of hours passing since switch was operated.
4. A syringe according to claim 1 , 2 or 3, characterised in that the stop watch counts the number of seconds passing immediately after the switch was operated.
- 25 5. Syringe according to anyone of the preceding claims, characterised in that the electronic representation is reproduced in an electronic display.
6. A syringe according to claim 5, characterised in that the display comprises twelve segments forming a circle.
- 30 7. A syringe according to claim 6, characterised in that the stop watch provides an activation of one segment for each hour passed after the switch was operated .

8. A syringe according to claim 6, characterised in that the stop watch during its running activates one or more segments per second passing immediately after the switch was operated until all segments of the dial is activated and thereafter deactivates the segments to reactivate one segment for each hour passing after the operation of the switch.

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9. A syringe according to claim 7, characterised in that two segments are activated per second.

10. A syringe according to anyone of the preceding claims, characterised in that it is equipped with a memory storing data comprising the sizes of a number of previously injected doses and  
10 the time intervals between these doses and the insulin type used by the injections.

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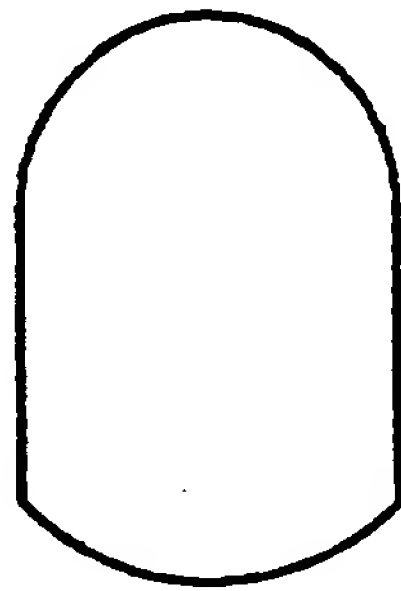


Fig. 1

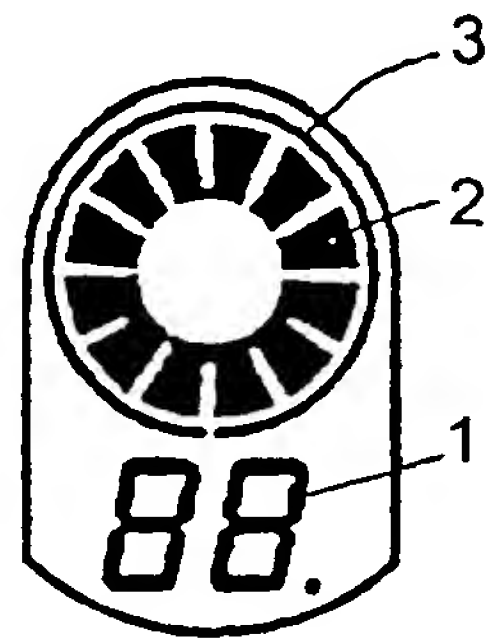


Fig 2

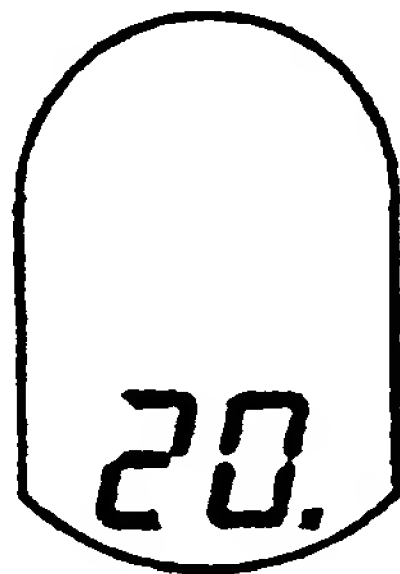


Fig. 3

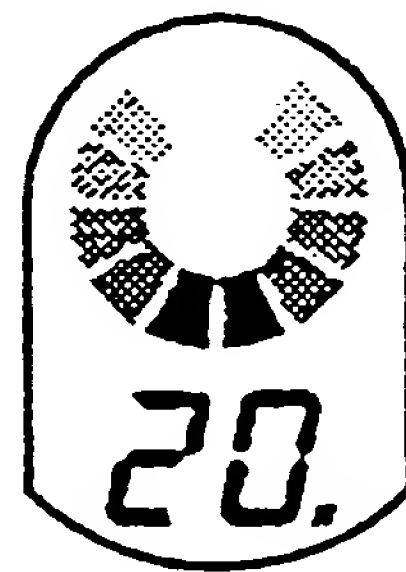


Fig. 4

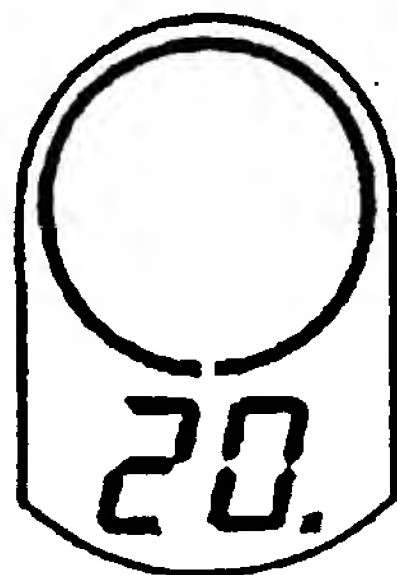


Fig. 5

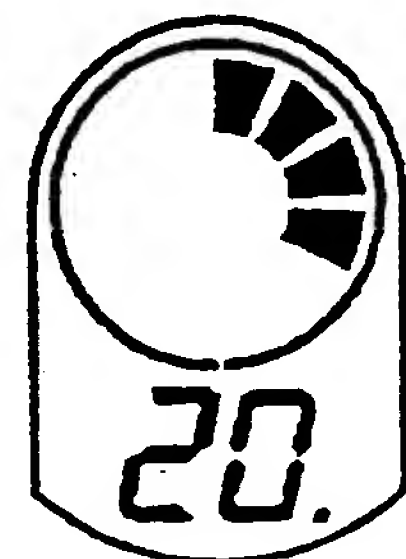


Fig. 6

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/DK 97/00077

## A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61M 5/178, A61M 5/20

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

DIALOG: WPI, CLAIMS

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 9524233 A1 (CASTELLANO, THOMAS, P. ET AL), 14 Sept 1995 (14.09.95), figure 1, abstract  -----	1-10



Further documents are listed in the continuation of Box C.



See patent family annex.

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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9524233 A1	14/09/95	AU 1939395 A	25/09/95
		EP 0749332 A	27/12/96
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		US 5593390 A	14/01/97
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